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DATE MAILED: 11/17/2006

| APPLICATION NO.      | FILING DATE    | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO |
|----------------------|----------------|----------------------|---------------------|-----------------|
| 10/564,863           | 01/17/2006     | Kozo Minamitani      | 0388-060112         | 5348            |
| 7:                   | 590 11/17/2006 |                      | EXAMINER            |                 |
| Webb Ziesenł         | neim Logsdon   |                      | CYGAN, M            | ICHAEL T        |
| Orkin & Hanso        | n .            |                      |                     |                 |
| 700 Koppers Building |                |                      | ART UNIT            | PAPER NUMBER    |
| 436 Seventh Avenue   |                |                      | 2855                |                 |
| Pittshurgh PA        | 15219-1818     |                      |                     |                 |

Please find below and/or attached an Office communication concerning this application or proceeding.

|   | Application No.   | Applicant(s)              |  |  |  |  |
|---|---|---------------------------|--|--|--|--|
| Office Action Summan  | 10/564,863  | MINAMITANI ET AL.         |  |  |  |  |
| Office Action Summary   | Examiner  | Art Unit                  |  |  |  |  |
|   | Michael Cygan   | 2855                      |  |  |  |  |
| The MAILING DATE of this communication appears on the cover sheet with the correspondence address<br>Period for Reply   |   |                           |  |  |  |  |
| A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.  - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).  Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). |   |                           |  |  |  |  |
| Status  |   |                           |  |  |  |  |
| 1) Responsive to communication(s) filed on  |   |                           |  |  |  |  |
| · ·   | action is non-final.  |                           |  |  |  |  |
| ·   | , —   |                           |  |  |  |  |
| closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.   |   |                           |  |  |  |  |
| Disposition of Claims   |   |                           |  |  |  |  |
| 4)⊠ Claim(s) <u>1-4</u> is/are pending in the application.  |   |                           |  |  |  |  |
| 4a) Of the above claim(s) is/are withdrawn from consideration.  |   |                           |  |  |  |  |
| 5) Claim(s) is/are allowed.   |   |                           |  |  |  |  |
| 6)⊠ Claim(s) <u>1-4</u> is/are rejected.  |   |                           |  |  |  |  |
| Claim(s) is/are objected to.  |   |                           |  |  |  |  |
| 8) Claim(s) are subject to restriction and/or election requirement.   |   |                           |  |  |  |  |
| Application Papers  |   |                           |  |  |  |  |
|   | r   |                           |  |  |  |  |
| 9) The specification is objected to by the Examiner.  10) The drawing(s) filed on 17 January 2006 is/are: a) □ accepted or b) □ objected to by the Examiner.  |   |                           |  |  |  |  |
| 10)⊠ The drawing(s) filed on <u>17 January 2006</u> is/are: a)⊠ accepted or b)□ objected to by the Examiner.  Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).   |   |                           |  |  |  |  |
|   |   |                           |  |  |  |  |
| Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.  |   |                           |  |  |  |  |
| Priority under 35 U.S.C. § 119  | animor. Note the attached Office                                  | Action of 1011111 10-102. |  |  |  |  |
| •   |   | (1) (2)                   |  |  |  |  |
| 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).   |   |                           |  |  |  |  |
| a) All b) Some * c) None of:  |   |                           |  |  |  |  |
| <u>=</u>  | 1. Certified copies of the priority documents have been received. |                           |  |  |  |  |
| 2. Certified copies of the priority documents have been received in Application No  |   |                           |  |  |  |  |
| 3. Copies of the certified copies of the priority documents have been received in this National Stage   |   |                           |  |  |  |  |
| application from the International Bureau (PCT Rule 17.2(a)).   |   |                           |  |  |  |  |
| * See the attached detailed Office action for a list of the certified copies not received.  |   |                           |  |  |  |  |
|   |   |                           |  |  |  |  |
| Attachment(s)   |   |                           |  |  |  |  |
| 1) Notice of References Cited (PTO-892)   | 4) Interview Summary  |                           |  |  |  |  |
| 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) Information Disclosure Statement(s) (PTO/SB/08)  | Paper No(s)/Mail Da<br>5) Notice of Informal P                    |                           |  |  |  |  |
| Paper No(s)/Mail Date   | 6) Other:   |                           |  |  |  |  |
|   |   |                           |  |  |  |  |

## **DETAILED ACTION**

## Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4 are rejected under 35 U.S.C. 102(a) as being anticipated by JP 2004-69325. The '325 publication discloses the claimed invention, a hole inspection system for a eye drop container(paragraphs 0001-0003), where the container [2] is pressed by pressing means (23) to blow air out of the hole and the pressure is determined in a connected sealed space (using sealing member 18) to calculate the hole diameter based upon the pressure and a threshold pressure (paragraphs 0015-0019). See entire document.

Claims 1-4 are rejected under 35 U.S.C. 102(b) as being anticipated by Calhoun (US 3,431,773). The claims are directed to an apparatus; limitations directed to use are given patentable weight only with regards to the structure imparted by the use. Here, claim 1 is directed to a hole inspection system. The system must be capable of being used with a pierced container, capable of being used with a container that is being compressed, capable of being used in a size determination; however, the claim does not require any structure to, for example, compress the container. Calhoun discloses a

hole inspection system comprising a chamber [16] holding a flexible container (oil can) capable of being pressed from the outside with compressed air [30,58], where the pressure of the air moving through the hole is measured by the connection of members [59,62] acting to connect at a threshold representing a maximum acceptable leak (hole size) limit. See Figure 2 and column 3 line 65 through column 4 line 69.

Claim 2 requires a pressure chamber formed by a sealing member. Calhoun discloses a sealing film [42 or 62] for sealing the aperture at the chamber and acting to detect the pressure therein; see column 3 line 65 through column 4 line 69.

Claim 3 recites the use of the invention with a medical fluid; since the apparatus of Calhoun possesses the structural features of operation with a fluid-containing body (oil-containing oil can), it possesses the structural features of operation with any type of iquid, including medical fluids.

Claim 4 recites the operational step of resetting a reference pressure before pressing; the apparatus disclosed by Calhoun is structurally capable of resetting the reference pressure (e.g., by changing the distance between electrode 59 and film 62).

## Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Cygan whose telephone number is (571) 272-2175. The examiner can normally be reached on 8:30-6 M-Th, alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Edward Lefkowitz can be reached on 571-272-2180. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MICHAEL CYGAM, PH.D.
PRIMARY EXAMINER